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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,834	04/24/2006	**Bernd Stahl**	0470-061191	2278

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,834	STAHL ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/13/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,20,25,26 and 31-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,20,25,26 and 31-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/13/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 05/13/09.

The amendment filed 05/13/09 affects the application, 10/576,834 as follows:

1. Claims 16 and 20 have been amended. Claims 21-24 have been canceled. New Claims 40-42 have been added. Applicant amendments have overcome the rejections made under 35 U.S.C. 103(a). However, the rejections made under 35 U.S.C. 112, first paragraph is maintained and a new ground(s) rejection is set forth herein below.
2. The responsive to applicants' amendment and arguments is contained herein below.

Claims 16, 20, 25, 26 and 31-42 are pending in application

Claim Objections

Claim 42 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 42 which is dependent on claim 16 recites the phrase "wherein the method is for the treatment of the immune system-related disorder". However, claims 16 is drawn to specific immune system-related disorder and not to immune system-related disorder in general.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 20, 25, 26 and 31-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4 in a mammal, comprising administering the said given oligosaccharide composition, does not reasonably provide enablement for preventing said diseases or conditions or reducing the risk of said diseases or conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

> (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.
>
> The nature of the invention: The instant invention pertains to a method for the treatment and or prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence and acquired immunodeficiency syndrome and/or human immunodeficiency virus infection in a

mammal, comprising administering to said mammal a composition comprising a therapeutically effective amount of a given specific oligosaccharide composition.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on treating, reduction of risk or preventing an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence and acquired immunodeficiency syndrome and/or human immunodeficiency virus infection in any mammal by administering a oligosaccharides composition to any mammal.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses the prevention the said diseases or conditions in any mammal, which are not known to have a single recognized cause. Applicants claims are drawn to a method for the prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4 in a mammal, comprising administering to said mammal a specific oligosaccharide composition, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which

makes up and identifies the claimed method for preventing the said diseases or conditions, or reducing the risk of said diseases or conditions, which is seen to be lacking a clear description via art recognized procedural and methodological steps. For example, an allergy is an abnormal response by the immune system. Allergies develop because of a mixture of inherited and environmental factors. In addition, the prevention of allergy such as allergy Type 1, allergy Type 2, allergy Type 3 and allergy Type 4 does not have a single recognized cause. For example, Allergies Type 1 which is also called contact allergy (and includes atopy, asthma, hay fever, eczema, food allergy and drug allergy) has several causes which include food, mold, animal dander, pollen, or dust. In fact, the aforementioned allergies are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the diet and maintenance of bodily healthiness which includes (1) genetic predisposition (2) exposition to allergen(s) and (3) family history of said disease. These are only a few of the factors that promote these diseases in people. Similarly, the prevention of immunosenescence, acquired immunodeficiency syndrome and human immunodeficiency virus infection in a mammal comprising administering to said mammal a composition (wherein these said diseases or conditions are characterized as having several causes and contributing factors), is not generally known to exist in this art and is also rejected herein. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the said disease can be prevented or how said risk can be reduced. It should also be noted that the reduction of risk of said diseases or conditions further supports the facts set forth above that pertains to the unpredictability of the instant claimed invention with respect to said prevention of said diseases or conditions.

Furthermore, a reduction of risk of said disease or condition is further not enabled since there are numerous contributing factors that promote the disease or condition and also since a risk (or reduction of risk) of having the disease or condition means that it is uncertain that the disease or condition would eventually definitely occur in the first place.

Thus, the skilled artisan would view that the prevention of the said diseases or conditions or the reduction of risk said diseases or conditions (which is characterized as having many contributing factors and causes) in any mammal by administering to said mammal the specific composition herein, as being highly *unpredictable*.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary: Moreover, it is noted that the specification does not provide any working examples.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the prevention of allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4 in a mammal, comprising administering to said mammal a specific oligosaccharide composition, in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of preventing said diseases or condition or, reducing the risk of said diseases or conditions of any mammal as recited in the instant claims suitable to practice the claimed invention. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method with a reasonable expectation of success. Therefore, the prevention or the reducing of the risk of allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4 in a

mammal, comprising administering to said mammal said specific oligosaccharide composition by said method is not enabled by the instant disclosure. It should be noted that claims 20, 25, 26 and 31-42 which are drawn to a method of preventing the said diseases or the reduction of risk said diseases or conditions are also encompassed by the aforementioned rejection.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation*, with no assurance of success.

Claims 16, 20, 25, 26 and 31-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, applicant claims "a method for the treatment, reduction of risk or prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4 in a mammal, comprising administering to said mammal a composition comprising a therapeutically effective amount of an acid oligosaccharide and at least two chemically distinct neutral oligosaccharides, wherein: the acid oligosaccharide has a degree of polymerization between 1 and 250 and is prepared from pectin or alginate; and the at least two chemically distinct neutral oligosaccharides comprise

fructooligosaccharides and a second oligosaccharide selected from the group consisting of transgalactooligosaccharides, galactooligosaccharides and mixtures thereof. However, the recitation of the language "reduction of risk" in the claim constitutes new matter as set forth in the claim. More specifically, the specification does not describe, disclose, provide or use any language or matter that pertains to or is equivalent to, the limitation "reduction of risk"" as recited in the claim. Furthermore, the introduction of the said language "reduction of risk" as set forth in claim 16, constitutes new matter. On the contrary, it should be noted that the specification describes treatment of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4. Moreover, the specification does not have support for the said language and consequently the claims contain new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16, 20-26, 31-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikemizu et al. (JP 2003221339 A, Abstract) in view of Okada et al. (EP 1321527 A1) and Nagura et al (British Journal of Nutrition (2002), 88, 421–426) and Miniello et al. (Acta paediatrica (Oslo, Norway : 1992). Supplement, (2003 Sep) Vol. 91, No. 441, pp. 68-760).

Claim 16 is drawn to a method for the treatment, reduction of risk or prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, and allergy Type 4 in a mammal, comprising administering to said mammal a composition comprising a therapeutically effective amount of an acid oligosaccharide and at least two chemically distinct neutral oligosaccharides, wherein: the acid oligosaccharide has a degree of polymerization between 1 and 250 and is prepared from pectin or alginate; and the at least two chemically distinct neutral oligosaccharides comprise fructooligosaccharides and a second oligosaccharide selected from the group consisting of transgalactooligosaccharides, galactooligosaccharides and mixtures thereof. Claims 20, 31-42 are drawn to the said method wherein acid and neutral oligosaccharides are of specific types, wherein the immune system-related disorder is a specific type including allergy types, wherein said method further comprises administering specific polyunsaturated fatty acid per day and wherein the composition comprises specific ingredients and are in specific food forms. Claims 25-26 are drawn to the said method wherein the composition is administered enterally and to humans of specific ages.

Ikemizu et al. disclose an anti-inflammatory agent useful as a pharmaceutical for treating atopic dermatitis that contains acidic xylo-oligosaccharide having uronic acid residue in xylooligo sugar-molecule, as active ingredient (see abstract). Furthermore, Ikemizu et al. disclose that the acidic is a mixed composition of an oligosaccharide having average polymerization degree (differing from xylose) of 2.0-11.0 (see abstract).

The difference between applicant's claimed method and the method suggested by Ikemizu et al. is that Ikemizu et al. do not exemplify the administration of the their composition

for treating an immune system-related disorder in a mammal and do not use a neutral oligosaccharide in their composition.

Okada et al. disclose that atopic dermatitis can be treated with an oligosaccharide raffinose (an α-galactosyl oligosaccharide or neutral oligosaccharide) (see col. 3, paragraph [0014]). Furthermore, Okada et al. disclose that allergic disease such as atopic dermatitis can be treated with an oligosaccharide containing α-galactosyl (an α-galactosyl oligosaccharide or neutral oligosaccharide) (see page 19-20, paragraphs [0108]-[0109]). In addition, Okada et al. disclose that their composition can be as pharmaceutical or as a functional food material (see page 19-20, paragraphs [0108]-[0109]).

Nagura et al. disclose that administration of raffinose improved atopic dermatitis in children and that raffinose has characteristics of prebiotics as well as other non-digestible oligosaccharides such as fructo-oligosaccharides and galactooligosaccharides (see page 88, left col. to right col. 1st paragraph). Furthermore, it should be noted that Nagura et al. disclose that the administration of raffinose to healthy volunteers resulted in a significant increase in faecal bifidobacteria and decrease of bacteroides and clostridia see abstract). This suggests that prebiotics such as fructo-oligosaccharides and galactooligosaccharides which have the similar characteristics or properties raffinose would improve or treat atopic dermatitis.

Miniello et al. disclose that Fructooligosaccharides(FOS) and trans-beta-galacto-oligosaccharides(TOS) have been claimed to benefit the health of the colon by selectively stimulating the growth of bifidobacteria and lactobacilli (prebiotic effect) and that it is supposed that specific bacteria in the gut microbial microflora could promote potentially antiallergenic processes and play a key part in atopic disease (e.g. atopic dermatitis) (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Ikemizu et al., Okada et al., Nagura et al. and Miniello et al., to treat atopic dermatitis (a Type 1 allergy) in an a mammal by administering to said mammal a composition comprising a combination of Ikemizu et al.'s acid oligosaccharide, Okada et al's neutral oligosaccharide and the Fructooligosaccharides(FOS), trans-beta-galacto-oligosaccharides(TOS) and galactooligosaccharides suggested by Nagura et al. and Miniello et al., since the combination of compounds that are used to treat the same diseases or conditions are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Ikemizu et al., Okada et al., Nagura et al. and Miniello et al., to treat atopic dermatitis (a Type 1 allergy) in an a mammal by administering to said mammal a composition comprising a combination of Ikemizu et al.'s acid oligosaccharide, Okada et al's neutral oligosaccharide and the Fructooligosaccharides(FOS), trans-beta-galacto-oligosaccharides(TOS) and galactooligosaccharides suggested by Nagura et al. and Miniello et al, since a skilled artisan would reasonable expect to use a composition comprising the combination of the compounds taught by Ikemizu et al., Okada et al., Nagura et al. and Miniello et al. for the same said purpose. It should be noted that the use of specific routes of administration such as enteral administration depends on factors such as the severity and location of the condition or disorder treated, the type, age and size of mammal. Also, it should be noted that the use specific food compositions, is also encompassed by this rejection since applicant's composition contains the same oligosaccharides

and since the preparation of food compositions including the food composition suggested by Okada et al. is common in the art and is well within the purview of a skilled artisan and depends on factors such as the type, age of the individuals to whom the composition is be administered.

Response to Arguments

Applicant's amendments have not overcome the enablement rejections pertaining to prevention of the specifically recited diseases by administering said oligosaccharide composition, as set forth above. Applicant's arguments with respect to the rejections of claims 16, 20, 25, 26 and 31-42 made under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection.

The Applicant argues that the specification admittedly enables the treatment of allergies. This, in turn, is recognized within the art as a means of lowering the risk and preventing the recited allergies. However, the lowering of risk does not equate to the prevention of allergies as recited. That is, the reduction of risk factors is not a prevention of, not a predictor of nor a cure for any diseases or condition. Also, a treatment of allergies is not recognized within the art as a means of lowering the risk and preventing the recited allergies, as argued by applicant. It should be noted that treating of allergies after it occurs is not a preventive method and does not prevent the allergies from recurring. Moreover and as example, an allergy is an abnormal response by the immune system. Allergies develop because of a mixture of inherited and environmental factors. In addition, the prevention of allergy such as allergy Type 1, allergy Type 2, allergy Type 3 and allergy Type 4 does not have a single recognized cause. For example, Allergies Type 1 which is also called contact allergy (and includes atopy, asthma, hay fever, eczema, food allergy and drug allergy) has several causes which include food, mold, animal dander, pollen, or

dust. In fact, the aforementioned allergies are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the diet and maintenance of bodily healthiness which includes (1) genetic predisposition (2) exposition to allergen(s) and (3) family history of said disease. These are only a few of the factors that promote these diseases in people (see also the above rejection).

The applicant argues that the invention prevents allergies by maintaining or restoring the Thl/Th2 balance (specification a page 4, lines 1-3). Therefore, Applicants have provided, at least in theory (which Applicants do not intend to be bound by), a description of how allergies can be prevented. However, maintaining or restoring the Thl/Th2 balance does not equate to the prevention of allergies. Moreover and as example, an allergy is an abnormal response by the immune system. Allergies develop because of a mixture of inherited and environmental factors. In addition, the prevention of allergy such as allergy Type 1, allergy Type 2, allergy Type 3 and allergy Type 4 does not have a single recognized cause. For example, Allergies Type 1 which is also called contact allergy (and includes atopy, asthma, hay fever, eczema, food allergy and drug allergy) has several causes which include food, mold, animal dander, pollen, or dust. In fact, the aforementioned allergies are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the diet and maintenance of bodily healthiness which includes (1) genetic predisposition (2) exposition to allergen(s) and (3) family history of said disease. These are only a few of the factors that promote these diseases in people. It should also be noted that the abstract submitted by applicant (see also the above rejection).

The Applicant argues that Ikemizu discloses acid xylooligosaccharide,3 which is not the recited acid oligosaccharide. Ikemizu's xylooligosaccharide has a xylose backbone where a

uronic acid residue is attached as a side chain.4 Xylooligosaccharides are made from xylose units. The uronic acid side chains disclosed in Ikemizu are glucuronic acid or 4-O-methyl-glucuronic acid; and therefore derived from glucose, not galactose, mannose or gulose.5 However, Ikemizu oligosaccharide is an acidic oligosaccharide with the same degree of degree of polymerization and which comprises the same uronic acid (glucuronic acid). In addition it should be noted that a recitation that the claim requires that the acid oligosaccharide be prepared from pectin or alginate does not render Applicant's oligosaccharide Ikemizu's oligosaccharide especially since pectin is known to contain xylose and the preparation of said pectin is not limited to any specifically defined reaction(s), reactants or even a number of particular defined steps.

The Applicant argues that the recited invention requires that the acid oligosaccharide be prepared from pectin or alginate. However, Ikemizu oligosaccharide is an acidic oligosaccharide with the same degree of degree of polymerization and which comprises the same uronic acid (glucuronic acid). In addition it should be noted that a recitation that the claim requires that the acid oligosaccharide be prepared from pectin or alginate does not render Applicant's oligosaccharide Ikemizu's oligosaccharide especially since pectin is known to contain xylose and the preparation of said pectin is not limited to any specifically defined reaction(s), reactants or even a number of particular defined steps.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the

examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
August 16, 2009.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623